

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 08 MAY 2006

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Applicant's or agent's file reference 66355-0007	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US05/02171	International filing date (day/month/year) 24 January 2005 (24.01.2005)	Priority date (day/month/year) 27 January 2004 (27.01.2004)	
International Patent Classification (IPC) or national classification and IPC IPC(7): H04B 7/00 and US Cl.: 455/41.2			
Applicant PEETERS, JOHN P.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 19 October 2005 (19.10.2005)		Date of completion of this report 20 January 2006 (20.01.2006)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Lewis G. West Telephone No. 571-272-2600	

Form PCT/IPEA/409 (cover sheet)(April 2005)

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-28 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
pages 29-37 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the drawings:
pages 1/23-23/23 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US05/02171**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-64</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-64</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-64</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:

Claims 1-64 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest that disclosed by the prior art.

Regarding claim 1, the applicant includes the subject matter of: A diagnostics system comprising: a flexible patch having an adhesive portion and adapted to be positioned on a surface; a radio frequency identification (RFID) tag and sensor module integrated with said patch and having an antenna, an RFID electronic chip, and at least one sensor, said RFID tag and sensor module responding to a stimulus by wirelessly transmitting and receiving, through the use of said antenna, signals that correspond to said stimulus; and a wireless RFID reader adapted to communicate through the use of multiple protocols with said RFID tag and sensor module, said RFID reader being adapted to communicate over a network through the use of multiple communication protocols. The above subject matter is disclosed by EVANYK et al (US 2004/0225199 A1) in view of DRINAN et al (US 2003/0004403 A1). However, the applicant overcomes the references due to the applicant's earlier priority date. Therefore, the applicant's invention of claim 1 comprises a unique combination of subject matter that is neither taught nor suggested by the prior art.

Regarding claim 12, the applicant includes the subject matter of: the patch includes at least one micro knife adapted to draw blood from said surface when said patch is pressed on said surface, wherein said surface is the skin surface of a person. It is noted that this subject matter is not disclosed by any of the cited references.

Regarding claim 14, the applicant includes the subject matter of: a substrate having a sample input port enabling migration of an analyte by capillary forces; and at least one testing area integrated with said substrate area and adapted to capture antigens that flow through said testing area. It is noted that this subject matter is not disclosed by any of the cited references.

Regarding claim 25, the applicant includes the subject matter of: A human diagnostics system comprising: a patch having a radio frequency identification (RFID) tag and sensor module, and being attachable to the surface of the skin and adapted to sense predetermined elements through the skin and transmit signals corresponding to said predetermined elements; a RFID reader communicative with said patch through the use of a network and adapted to analyze, receive, and transmit the signals from said patch through the use of multiple protocols; and a remote storage and data unit communicative with said RFID reader, said remote storage and data unit analyzing and storing data from said patch and said RFID, said remote storage and data unit transmitting said analyzed and stored data to said RFID reader through the use of said network. The above subject matter is disclosed by EVANYK et al (US 2004/0225199 A1) in view of DRINAN et al (US 2003/0004403 A1). However, the applicant overcomes the references due to the

Supplemental Box

applicant's earlier priority date. Therefore, the applicant's invention of claim 25 comprises a unique combination of subject matter that is neither taught nor suggested by the prior art.

Regarding claim 30, the applicant includes the subject matter of: A personal wireless communications device for communicating with a radio frequency identification (RFID) tag and sensor module, comprising: a multi protocol REID reader that is compatible with and adapted to activate said RFID tag and sensor module; a microprocessor communicative with said RFID reader and adapted to analyze and store data read by said RFID reader; and at least one antenna coupled to said microprocessor for transmitting and receiving data from said RFID reader, said microprocessor and said RFID tag and sensor module, said antenna being adapted to transmit and receive data from an external device through the use of a network. The above subject matter is disclosed by EVANYK et al (US 2004/0225199 A1) in view of DRINAN et al (US 2003/0004403 A1). However, the applicant overcomes the references due to the applicant's earlier priority date. Therefore, the applicant's invention of claim 30 comprises a unique combination of subject matter that is neither taught nor suggested by the prior art.

Regarding claim 35, the applicant includes the subject matter of: A diagnostics system comprising: a patch having an adhesive portion and adapted to be embedded within a structure; a radio frequency identification (RFID) tag and sensor module having an integrated temperature module, said RFID tag and sensor module being integrated with said patch and having an antenna and at least one sensor, said RFID tag and sensor module responding to a stimulus by wirelessly transmitting and receiving, through the use of said antenna, signals that correspond to said stimulus; and a wireless RFID reader communicative with said RFID tag and sensor module, said reader being adapted to communicate over a network through the use of multiple protocols. The above subject matter is disclosed by EVANYK et al (US 2004/0225199 A1) in view of DRINAN et al (US 2003/0004403 A1). However, the applicant overcomes the references due to the applicant's earlier priority date. Therefore, the applicant's invention of claim 35 comprises a unique combination of subject matter that is neither taught nor suggested by the prior art.

Regarding claim 38, the applicant includes the subject matter of: An immunoassay test strip system for use in conducting diagnostic measurements comprising: a substrate that forms a test strip; at least one test area located on said substrate for capturing antigens; and a radio frequency identification (RFID) tag and sensor module integrated with said substrate, said RFID tag and sensor module being adapted to sense and transmit signals that correspond to the antigens captured by said at least one test area. The above subject matter is disclosed by WHELAN et al (US 2005/0009122 A1). However, the applicant overcomes the references due to the applicant's earlier priority date. Therefore, the applicant's invention of claim 38 comprises a unique combination of subject matter that is neither taught nor suggested by the prior art.

Regarding claim 43, the applicant includes the subject matter of: the test strip is adapted to perform quantitative protein measurements. It is noted that this subject matter is not disclosed by any of the cited references.

Regarding claim 48, the applicant includes the subject matter of: A method of manufacturing a pathogen-specific radio frequency identification (RFID) tag and sensor module, comprising the steps of: providing a substrate; printing conductive leads on said substrate wherein said conductive leads define a sensor area; printing a protective cap doped with a material that is sensitive to pathogen specific enzymatic action within said sensor area; printing an antenna on said substrate; and integrating an REID tag and sensor module with said substrate. It is noted that this subject matter is not disclosed by any of the cited references. Therefore, the applicant's invention of claim 48 comprises a unique combination of subject matter that is neither taught nor suggested by the prior art.

Regarding claim 59, the applicant includes the subject matter of: A Lab-on-a-Chip microfluidics sensor for conducting rapid diagnostic measurements that are readable directly with a remote wireless RF reader comprising: conductive leads that enable transmission of signals; a Lab-on-a-Chip substrate having at least one test area integrated therein and a sensor interface that couples said conductive leads to said test area; a temperature module integrated with said substrate and adapted to generate signals that correspond to temperature; an addressable radio frequency (RF) chip having a controller, an RF power source with a voltage stabilization circuit, and a communication interface, said RIF chip receiving signals from said conductive leads and said temperature module, said RIF chip being adapted to process said conductive lead signals, said temperature module signals and signals from the wireless RIF reader, and at least one antenna adapted to receive signals from the wireless RIF reader and said RF chip and transmit signals from said Lab-on-a-Chip microfluidics sensor. It is noted that this subject matter is not disclosed by any of the cited references. Therefore, the applicant's invention of claim 59 comprises a unique combination of subject matter that is neither taught nor suggested by the prior art.

Regarding claim 63, the applicant includes the subject matter of: An immunoassay test strip for conducting an instant diagnostics test using a wireless reader device, wherein the wireless reader device is adapted to communicate over a wireless network, the immunoassay test strip comprising: at least one test area with an integrated radio frequency chip that is communicative with the wireless device and that provides power to said test area; and wherein said test area is an electro-immunoassay for measuring the presence and quantity of a biological molecule. The above subject matter is disclosed by WHELAN et al (US 2005/0009122 A1). However, the applicant overcomes the references due to the applicant's earlier priority date. Therefore, the applicant's invention of claim 63 comprises a unique combination of subject matter that is neither taught nor suggested by the prior art.

Claims 1-64 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.